

Food and Drug Administration, HHS

§ 864.8540

(presence in the plasma of functionally defective fibrinogen).

(b) *Classification*. Class II (performance standards).

[45 FR 60629, Sept. 12, 1980]

§ 864.8150 Calibrator for cell indices.

(a) *Identification*. A calibrator for cell indices is a device that approximates whole blood or certain blood cells and that is used to set an instrument intended to measure mean cell volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC), or other cell indices. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60631, Sept. 12, 1980]

§ 864.8165 Calibrator for hemoglobin or hematocrit measurement.

(a) *Identification*. A calibrator for hemoglobin or hematocrit measurement is a device that approximates whole blood, red blood cells, or a hemoglobin derivative and that is used to set instruments intended to measure hemoglobin, the hematocrit, or both. It is a material whose characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60632, Sept. 12, 1980]

§ 864.8175 Calibrator for platelet counting.

(a) *Identification*. A calibrator for platelet counting is a device that resembles platelets in plasma or whole blood and that is used to set a platelet counting instrument. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60633, Sept. 12, 1980]

§ 864.8185 Calibrator for red cell and white cell counting.

(a) *Identification*. A calibrator for red cell and white cell counting is a device that resembles red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60634, Sept. 12, 1980]

§ 864.8200 Blood cell diluent.

(a) *Identification*. A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60635, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 864.8500 Lymphocyte separation medium.

(a) *Identification*. A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60636, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.8540 Red cell lysing reagent.

(a) *Identification*. A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60636, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]